IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION MDL NO. 2327

Jo Huskey and Allen Huskey,
Plaintiffs,

v. Case No. 2:12-cv-05201

Ethicon, Inc. et al.,
Defendants

DEFENDANTS' NON-RETAINED EXPERT DISCLOSURES

Defendants Ethicon, Inc. and Johnson & Johnson, pursuant to Pretrial Order #73 and F.R.C.P. 26(a)(2)(c), provide the following written disclosures for Dr. Piet Hinoul, Dr. Axel Arnaud, and Dr. David Robinson.[1]

Dr. Piet Hinoul

Dr. Piet Hinoul will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a urogynecologist and Ethicon Medical Director, his clinical experience, review of literature, and the deposition testimony he has given in this litigation. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705.

Dr. Hinoul is a trained urogynecologist who has implanted hundreds of TVT devices, has performed hundreds of stress urinary incontinence (SUI) procedures, and has provided training and been involved with the training on the TVT products. While a clinician, Dr. Hinoul's

[1] A separate disclosure will be served concerning the testimony of Dr. Thomas Barbolt.

clinical practice included the repair of incontinence and pelvic floor repairs for women. He has served as an investigator and author on several studies and publications involving mid-urethral slings. In 2008, Dr. Hinoul joined Ethicon as the medical affairs director, with responsibilities for pelvic floor repair and incontinence repair products. His duties as medical director included making benefit/risk analyses of devices, drafting clinical evaluation reports, assessing clinical literature, speaking at panel meetings, reviewing adverse events, new product development, corresponding with physicians regarding the use of incontinence and pelvic floor products and providing medical input on the Instructions for Use (IFU), patient brochures, marketing professional education and design verification materials, and other Ethicon documents needing medical affairs' input.

Dr. Hinoul was trained on incontinence repairs including the TVT devices, and the associated risks. In addition to this training, Dr. Hinoul has performed hundreds of SUI repairs, including the TVT devices, has kept apprised of the literature on TVT and other SUI repairs, and has reviewed adverse event reports for these and other procedures. As a result, Dr. Hinoul knows the appropriate indications, procedural steps, warnings and adverse events that would be associated with the TVT devices, and he is expected to testify that the TVT-O IFU is appropriate.

As a practicing urogynecologist and as medical affairs director for Ethicon, Dr. Hinoul has personally determined that the benefits of TVT-O far outweigh the risks. In reaching this determination, he relied upon his clinical experience, training, education, cadaver labs, his review of the applicable literature and the documents that led to the launch of TVT and TVT-O. In his role as medical affairs director, Dr. Hinoul has prepared clinical expert reports on the TVT devices including the TVT-O and has provided medical advice on the benefit/risk assessment of

TVT-O. Dr. Hinoul agrees with the current literature and published professional organization position statements that TVT and TVT-O along with other mid-urethral slings are the standard of care, gold standard and treatment of choice for the surgical treatment of SUI in women, and they have been so for many years.

Dr. Hinoul is expected to provide testimony as to Ethicon's basis for manufacturing and selling TVT and TVT-O. More specifically, incontinence is a prevalent condition that can severely affect a woman's quality of life. Ethicon desired to provide a product that would help women. The surgical procedures available to treat SUI before the TVT devices were developed (Burch colposuspension, fascial slings, Marshall-Marchetti-Kranz, colporrhaphy and other procedures) were associated with increased morbidity, longer recovery times, lower success rates and lack of long-term durability. Dr. Hinoul may also provide testimony regarding other SUI procedures and why the TVT devices are an important and appropriate treatment option compared to those other procedures. In working with Dr. Ulmsten, Ethicon wanted to provide a device that would change the way incontinence was treated, and to present women with a minimally invasive, safe, effective, and durable repair.

Dr. Hinoul will provide the history of the development of the TVT and TVT-O. Dr. Hinoul will testify that Dr. Ulmsten assessed several different meshes to determine which was the most appropriate for SUI repair, and he concluded that it was the Prolene mesh. Using an integral theory, applying the Prolene mesh tension-free in the mid-urethra, with a retropubic approach, Dr. Ulmsten developed the TVT. The Prolene mesh had been used in the human body since 1974, and in sutures since 1969, for cardiovascular repair and many other surgical procedures. The mesh had been used safely in the body for decades, and Dr. Ulmsten demonstrated its success in supporting the mid-urethra. Dr. Ulmsten performed several clinical

trials in which TVT was shown to be safe and effective. In 1997, Ethicon sold TVT in Europe. Then in 1998, with the support of over two years of data, several clinical studies and demonstrated success in Europe, Ethicon began to sell TVT in the United States. Ethicon entered into agreements with Dr. Ulmsten's company, Medscand, to sell the TVT. Dr. Hinoul will testify that these agreements did not alter the factual data presented in the 1998 multi-center study. He will also testify that the universe of data available today further confirms the outcomes of Ulmsten's early studies. By the early 2000s, there was 5-year data and numerous published articles identifying TVT as the "gold standard" for surgical SUI repair, and TVT remains the "gold standard" today.

Dr. Hinoul may also testify that, in 2001, a transobturator approach to treat SUI was developed and sold by American Medical Systems. This approach provided physicians the option of a mid-urethral sling with a transobturator "outside in" approach. Dr. DeLeval subsequently began using the Prolene Mesh for a transobturator sling with an inside out approach. Ethicon working with Dr. DeLeval developed the TVT-Obturator (TVT-O) which was cleared by the FDA and sold in January 2004. Dr. Hinoul will opine that mid-urethral slings with either a retropubic or obturator pass, which include TVT and TVT-O, are the standard of care for SUI repair. He will further opine that TVT and TVT-O provide physicians with two safe and effective approaches to correct SUI, and both remain on the market today.

Dr. Hinoul will testify that there many long term studies on the TVT and TVT-O, which include over 100 RCTs on TVT, 60 RCTs on TVT-O, over 1000 studies on the TVT devices and over 2000 on mid-urethral slings. TVT is the most studied device for the surgical treatment of SUI, with the longest period of supporting clinical data. The major professional societies for the treatment of SUI (American Urological Association, American Urogynecologic Society,

International Urogynecology Association, International Incontinence Society, National Institute of Health and Care Excellence, the British Association of Urological Surgeons, SUF, and other professional organizations) uniformly hold that mid-urethral slings are the treatment of choice, standard of care or gold standard for SUI. The studies have further shown that TVT and TVT-O have an overall positive effect on sexual function, in some cases relieve urge incontinence, is effective in obese patients, provide significant improvement in quality of life, are safe and effective, and can be – and have been – used across the world with great results.

Dr. Hinoul came to Ethicon shortly before publication of the 2008 Public Health Notice and he spoke at the September 2011 FDA ADCOM hearings following publication of the 2011 Public Health Notice. He will provide testimony regarding Ethicon's responses to such Public Health Notices, and he is expected to opine that FDA limited the warnings such that they do not include mid-urethral slings. Further, that the FDA came out with a position statement in 2013 that the multi-incisional slings (including TVT and TVT-O) are safe, effective and have low erosion rates.

In Dr. Hinoul's position as medical affairs director for Ethicon, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Hinoul will testify that physicians must use their training, experience and education when reading an IFU and when implanting TVT-O or any other device. Dr. Hinoul will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the TVT-O IFU was appropriately written as to the sections for: indications, procedural steps, warnings, adverse reactions, contraindications and actions. More specifically, the IFU properly indicates TVT-O to correct urethral hypermobility and intrinsic sphincter deficiency leading to SUI. There are numerous

studies supporting the use of TVT and TVT-O for the repair of both mechanisms of SUI. Dr. Hinoul will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons who are trained to treat SUI and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Hinoul will provide testimony regarding the procedural steps for TVT-O and the reasons why the procedural steps were provided as they were. He will also provide testimony as to how Ethicon instructed physicians to place and adjust the TVT mesh, and to ensure the mesh is placed tension-free under the urethra.

Dr. Hinoul will provide testimony regarding the adequacy of the contraindication, warnings, the adverse reactions, and actions sections. He will specifically provide testimony as to why specific warnings and adverse reactions were or were not provided. Further, Dr. Hinoul will testify that the IFU is intended to identify the specific adverse reactions that may occur from the TVT-O device, and he will opine that the TVT-O IFU did so. Dr. Hinoul will further testify that chronic pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs.

In Dr. Hinoul's position as medical affairs director he is sometimes called upon to participate in the copy-review of patient brochures and other marketing material and provide input from a medical perspective. Dr. Hinoul may give testimony regarding the accuracy and appropriateness of such documents from a medical perspective.

Prior to coming to Ethicon, Dr. Hinoul served as a professional education preceptor for Ethicon. In that position, Dr. Hinoul trained physicians on pelvic floor surgery using mesh products. Thereafter, in his role as medical affairs director, Dr. Hinoul became further involved

with Ethicon's professional education program. His responsibilities in that regard involved reviewing professional education material to ensure its accuracy and appropriateness, and to facilitate education. Relying upon this knowledge and experience, Dr. Hinoul may provide testimony regarding Ethicon's professional education program, the procedural steps, clinical literature, IFU, complications, success rates, and any other medical portions of the professional education provided for TVT and TVT-O. Dr. Hinoul will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships. He may further offer testimony and opinions from the perspective of a professional education trainer prior to coming to Ethicon. Such testimony may specifically include the adequacy of Ethicon's professional education training. Dr. Hinoul may also provide testimony on yearly Summits.

In his role as medical affairs director, Dr. Hinoul was apprised of the certificates that were provided to professional education trainees, and he will testify that these certificates were simply acknowledgments of attendance and not a certification of the physician's ability to perform the surgery. Dr. Hinoul will further opine that it is the surgeon's responsibility to determine whether he or she is capable of performing any surgery, and that credentialing takes place by professional organizations or hospitals, not by manufacturers.

In Dr. Hinoul's role as a medical director and as a physician, he is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. Hinoul may offer testimony and opinions about the design of the TVT devices and how they safely traverse the pelvic floor. Dr. Hinoul was also involved in the continued studies of the mesh that was used in TVT and TVT-O, as well as other potential new meshes for SUI. Dr. Hinoul, on behalf of Ethicon, assessed lighter weight meshes for TVT and

TVT-O including but not limited to TVT-O PA and Scion, and determined that they were inferior in the support they provided, their placeability, and their configuration once implanted. Dr. Hinoul will further testify on behalf of Ethicon's medical affairs as to why Ethicon continued to use the Prolene mesh in the TVT devices instead of adopting a different mesh. Dr. Hinoul has continued to review the literature on other procedures and devices including laparoscopic burch and fascial slings, and has concluded that TVT-O and other mid-urethral slings remain the treatment of choice.

Dr. Hinoul may provide testimony with regard to the pore size and weight of the Prolene mesh, including the other material characteristics of other meshes on the market to be able to show that Ethicon still has one of the largest pore meshes on the market, and that the weight and strength of the Prolene Mesh is necessary to properly support the urethra to prevent incontinence.

Additionally, in both his clinical practice and in his role as medical affairs director, Dr. Hinoul assessed the tissue reaction, integration, contraction and compliance of mesh in-vivo, and determined that the benefits of TVT and TVT-O outweighed the risks. Dr. Hinoul may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolene mesh in TVT and TVT-O integrates well in the body, that contraction rates are not clinically significant and cannot be compared to other more-invasive surgeries, and that TVT is appropriately compliant in the body.

Dr. Hinoul also assessed complication rates for the TVT devices while in clinical practice and at Ethicon. Dr. Hinoul may therefore testify about the adverse reactions that are associated with the TVT and TVT-O and other surgical procedures to show why Ethicon continues to believe that the benefits of TVT-O outweigh the risks. Dr. Hinoul will also testify, based upon

his clinical practice and review of the adverse event reports and literature, as to the rate of occurrence of adverse events, and why he believes that serious complication rates are uncommon. More specifically, Dr. Hinoul will opine that both the applicable literature and his experience in practice support an overall 1-2% exposure rate for TVT. He will further testify that, of the 1-2%, some exposures can be treated conservatively or with no treatment at all, while other patients may need to have a small portion of the mesh excised. Dr. Hinoul will testify that it is extremely rare that the whole of the mesh must be taken out. Groin pain with the TVT-O and other obturator slings is usually transient, and persistent groin pain is a low risk that is warned of. Dr. Hinoul will testify bladder perforations are largely avoided with the TVT-O. Dr. Hinoul will provide testimony regarding all potential complications along with the success and safety data on the TVT and TVT-O.

In Dr. Hinoul's benefit/risk analysis for TVT and TVT-O, he assessed that laser cut and mechanical-cut mesh were both appropriate, and there is not clinical evidence that either product is safer than the other. He further determined and may opine that the laser cut mesh did not cause a clinically significant impact on patients and that any particle loss associated with mechanical cut mesh likewise had no clinical effect on patients. Dr. Hinoul will further testify that degradation, if it exists, is not clinically significant and there are not studies to show degradation, even if it were to exist causes any harm to patients. It is this Prolene mesh that has been used in hernia meshes for decades safely.

Dr. Hinoul may also testify, from a design perspective, to any design documents for TVT and TVT-O, or any other topic on which he has been identified as a corporate witness on behalf of Ethicon.

Dr. Axel Arnaud

Dr. Axel Arnaud will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a general surgeon and as European Ethicon Medical Director, his clinical experience, his review of literature, and the deposition testimony he has given in this litigation. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705. In addition, any portion of Dr. Arnaud's deposition testimony concerning these matters or the matters identified below may be designated by Ethicon for use at trial, and such deposition testimony may likewise involve or require scientific, technical or specialized knowledge falling within the scope of F.R.E. 702, 703, or 705.

Dr. Axel Arnaud obtained his medical degree in 1978, and completed his residency in surgery for general and digestive surgery in 1984 at the University of Merseille. Dr. Arnaud was an assistant professor of anatomy from 1979-1981 and an assistant professor of general and digestive surgery from 1984-1988. Dr. Arnaud was a practicing surgeon in France until he joined Ethicon in 1992. Dr. Arnaud held the positions of Director of Research and Development until 1999, Scientific Director for Ethicon Europe until 2001, Scientific Director for Gynecare Europe until 2008, Medical Affairs Director for Ethicon EMEA until 2013, and he is currently the Medical Affairs Group Director for Global Surgery EMEA.

As a practicing clinician, Dr. Arnaud was responsible for making benefit/risk analyses regarding medical devices. His duties as a European medical director for Ethicon further included making benefit/risk analyses of devices including TVT and TVT-O, assessing clinical literature, speaking at panel meetings, and providing medical input on the Instructions for Use (IFU) and other Ethicon documents needing medical affairs' input.

Dr. Arnaud's surgical experience, review of medical literature, experience with cadaver labs, review of SUI procedures, and consultations with other experts in SUI repair has given him the expertise to identify the appropriate indications, procedural steps, warnings and adverse events that would be associated with the TVT devices, and he is expected to testify that the TVT-O IFU is appropriate.

As a surgeon and as the European medical affairs director for Ethicon, Dr. Arnaud determined that the benefits of TVT and TVT-O far outweigh the risks. Dr. Arnaud further agrees with the current literature and published professional organization statements that TVT and other mid-urethral slings including TVT-O are the standard of care for the surgical treatment of SUI in women, and they have been so for many years.

Dr. Arnaud is expected to provide testimony as to Ethicon's basis for manufacturing and selling TVT and TVT-O. More specifically, he will testify that incontinence is a prevalent condition that can severely affect a woman's quality of life. Ethicon desired to provide a product that would help women. The surgical procedures available to treat SUI before the TVT devices were developed were associated with increased morbidity, longer recovery times, lower success rates and a lack of long-term durability. Dr. Arnaud may also provide testimony as to why the TVT devices are an important and appropriate treatment option for women with SUI.

Dr. Arnauld will testify concerning the history and development of TVT and TVT-O. Dr. Arnaud will testify regarding his meetings with Dr. Ulmsten, his opinions of TVT when it was demonstrated for him, and the reasons why he encouraged Ethicon to support Dr. Ulmsten in marketing TVT globally. Dr. Ulmsten and Ethicon wanted to provide a device that would change the way incontinence was treated, and to present women with a minimally invasive, safe,

effective, and durable repair. Dr. Ulmsten assessed several different meshes to determine which was the most appropriate for SUI repair, and he concluded that it was the Prolene mesh. Using an integral theory, applying the Prolene mesh tension-free in the mid-urethra, with a retropubic approach, Dr. Ulmsten developed the TVT. The Prolene mesh had been used in the human body since 1974, and in sutures since 1969, for cardiovascular repair and many other surgical procedures. The mesh had been used safely in the body for decades, and Dr. Ulmsten further demonstrated its success in supporting the mid-urethra. Dr. Arnaud visited with Dr. Ulmsten, watched the procedures, spoke with patients, communicated with outside consultants, and determined that the TVT procedure was safe, effective and would revolutionize the way in which SUI repairs were performed.

Dr. Ulmsten performed several clinical trials in which TVT was shown to be safe and effective. In 1997, Ethicon sold TVT in Europe. The feedback regarding the safety and effectiveness was outstanding. Then in 1998, with the support of over two years of data, several clinical studies and demonstrated success in Europe, Ethicon began to sell TVT in the United States. Ethicon entered into agreements with Dr. Ulmsten's company, Medscand, to sell the TVT. Dr. Arnaud will testify that these agreements did not alter the factual data presented in the 1998 multi-center study. He will also testify that the universe of data available today further confirms the outcomes of Ulmsten's early studies. By the early 2000s, there was 5-year data and numerous published articles identifying TVT as the "gold standard" for surgical SUI repair. Dr. Arnaud will testify that TVT remains the worldwide "gold standard" today.

Dr. Arnaud may also testify that, in 2001, a transobturator approach to treat SUI was developed and sold by American Medical Systems. This approach provided physicians the option of a transobturator pass to place a mesh sling below the mid-urethra. In 2002, Dr. Arnaud

met with Dr. DeLeval about an inside-out transobturator approach. Dr. Arnaud reviewed the procedure, brought in experts, reviewed literature and data, and determined it was a safe and effective procedure. In 2003, Ethicon began to sell the TVT-Obturator (TVT-O), which was an inside-out transobturator approach. Dr. Arnaud will opine that mid-urethral slings with either a retropubic or transobturator pass, including TVT and TVT-O, are the standard of care for SUI repair. He will further opine that TVT and TVT-O provide physicians with two safe and effective approaches to correct SUI. Both remain on the market today.

Dr. Hinoul will testify that there many long term studies on the TVT and TVT-O, which include over 100 RCTs on TVT, 60 RCTs on TVT-O, over 1000 studies on the TVT devices and over 2000 on mid-urethral slings. TVT is the most studied device for the surgical treatment of SUI, with the longest period of follow-up data. The major professional societies for the treatment of SUI (American Urological Association, American Urogynecologic Society, National Institute of Health and Care Excellence, International Continence Society, International Urogynecology Association, British Association of Urological Surgeons, SUFU and others) uniformly hold that mid-urethral slings are the treatment of choice, standard of care and gold standard for SUI. The studies have further shown that TVT and TVT-O have an overall positive effect on sexual function, in some cases relieve urge incontinence, are appropriate in obese women, are safe and effective, and can be – and have been – used across the world with great results.

In Dr. Arnaud's position as European medical affairs director, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Arnaud will testify that physicians must use their training, experience and education when reading an IFU and when implanting TVT-O or any

other device. Dr. Arnaud will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the TVT-O IFU was appropriately written. Dr. Arnaud will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons who are trained to treat SUI and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Arnaud will provide testimony regarding the adequacy of the warnings and adverse reactions in the IFU. Further, Dr. Arnaud will testify that the IFU is intended to identify the specific adverse reactions that may occur from the TVT-O device, and he will opine that the TVT-O IFU did so. Dr. Arnaud will further testify that pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs.

Dr. Arnaud may provide testimony regarding Ethicon's decision to make laser cut mesh an option, and he will opine that laser cut and mechanical cut mesh did not lead to clinically significant differences, and that the mechanical cut mesh was appropriate for use in the body, as the long term data provides.

Dr. David Robinson

Dr. David Robinson may provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a pelvic floor surgeon and Ethicon Medical Director, his clinical experience, review of literature, and the deposition testimony he has given in this litigation. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705. In addition, any portion of Dr. Robinson's deposition testimony concerning these matters or the matters identified below may be designated by Ethicon for use at trial, and such deposition testimony may likewise involve or require scientific, technical or specialized knowledge falling within the scope of F.R.E. 702, 703, or 705.

Dr. Robinson performed a residency in obstetrics and gynecology and completed additional training for pelvic floor surgery. He has implanted hundreds of TVT devices, has performed hundreds of stress urinary incontinence (SUI) procedures, and has trained physicians to use the TVT products. Dr. Robinson's clinical practice included the repair of incontinence for women. He has also served as an investigator for pelvic mesh repair studies. In 2005, Dr. Robinson joined Ethicon as the medical affairs director, with responsibilities for pelvic floor repair and incontinence repair products. His duties as medical director included making benefit risk analyses of devices, drafting clinical evaluation reports, assessing clinical literature, speaking at panel meetings, reviewing adverse events, and providing medical input on the Instructions for Use (IFU), patient brochures, marketing professional education and design verification materials, and other Ethicon documents needing medical affairs' input.

Dr. Robinson was trained on incontinence repairs including TVT and TVT-O, and the associated risks. In addition to this training, Dr. Robinson performed hundreds of SUI repairs, including TVT, kept apprised of the literature on TVT and other SUI repairs while an active

surgeon and in the role of medical affairs director overseeing pelvic floor products, and has reviewed adverse event reports for TVT and other pelvic devices during his time as medical director overseeing pelvic floor products. As a result, Dr. Robinson knows the appropriate indications, procedural steps, warnings and adverse events that would be associated with the TVT devices, and he is expected to testify that the TVT-O IFU is appropriate.

As a practicing surgeon for pelvic floor defects including urinary incontinence and as medical affairs director for Ethicon, Dr. Robinson personally determined that the benefits of TVT-O far outweigh the risks. In reaching this determination, he relied upon his clinical experience, training, education, experience with cadaver labs, and his review of the applicable literature and the documents that led to the launch of TVT and TVT-O. In his role as medical affairs director, Dr. Robinson has prepared clinical expert reports on TVT and TVT-O and has provided medical advice on the benefit risk assessment of TVT. Dr. Robinson agrees with the current literature and published professional organization statements that TVT and other mid-urethral slings including TVT-O are the standard of care for the surgical treatment of SUI in women, and they have been so since the early 2000s.

Dr. Robinson may provide testimony as to Ethicon continuing to manufacture and sell TVT and TVT-O, and why Dr. Robinson provided TVT and TVT-O to his patients. More specifically, he will testify that incontinence is a prevalent condition that can severely affect a woman's quality of life. Ethicon desired to continue to provide a product that would help women. The other surgical procedures available to treat SUI (Burch colposuspension, fascial slings, Marshall-Marchetti-Kranz, colporrhaphy and other procedures) were associated with increased morbidity, longer recovery times, lower success rates and lack of long-term durability. Dr. Robinson may also provide testimony regarding those other SUI procedures and why the

medical affairs department believed the TVT devices were an important and appropriate treatment option compared to them. Dr. Robinson is further expected to opine that non-surgical options for more severe SUI do not provide long-lasting success.

Dr. Robinson will testify that by the early 2000s, there was 5-year data and numerous published articles identifying TVT as the "gold standard" for surgical SUI repair, and he will opine that TVT continued to be the gold standard while he was in his role as medical affairs director.

Dr. Robinson will testify that there was, numerous RCTs and multiple other studies that supported Ethicon's continued sale of TVT and TVT-O while Dr. Robison was medical director. Further, Dr. Robinson will testify that TVT and TVT-O were and still are the most studied devices for the surgical treatment of SUI, with the longest period of supporting clinical data. The major professional societies for the treatment of SUI (American Urological Association, American Urogynecologic Society, National Institute of Health and Care Excellence, International Urogynecological Association, International Continence Society, SUFU and others) uniformly hold that mid-urethral slings are the repair of choice for SUI. The studies have further shown that TVT and TVT-O do not have an overall negative effect on sexual function, in some cases relieve urge incontinence, and can be – and have been – used across the world with great results.

In Dr. Robinson's position as medical affairs director for Ethicon, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Robinson will testify that physicians must use their training, experience and education when reading an IFU and when implanting TVT-O or any

other device. Dr. Robinson will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the TVT-O IFU was appropriately written as to the sections for: indications, procedural steps, warnings, adverse reactions, contraindications and actions. More specifically, the IFU properly indicates TVT to correct urethral hypermobility and intrinsic sphincter deficiency leading to SUI. There are numerous studies supporting the use of TVT and TVT-O to repair both mechanisms of SUI. Dr. Robinson will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons, who are trained to treat SUI, and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Robinson will provide testimony regarding the procedural steps for TVT-O and the reasons why the procedural steps were provided as they were. He will also provide testimony as to how Ethicon instructed physicians to place and adjust the TVT mesh, and to ensure the mesh is placed tension-free under the urethra.

Dr. Robinson will provide testimony regarding the adequacy of the warnings, the adverse reactions, and actions sections in the TVT-O IFU. He will also testify as to why specific warnings and adverse reactions were or were not provided. Further, Dr. Robinson will testify that the IFU is intended to identify the specific adverse reactions that may occur from the TVT-O device, and he will opine that the TVT-O IFU did so. Dr. Robinson will further testify that pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs.

In Dr. Robinson's position as medical affairs director he was sometimes called upon to participate in the copy-review of patient brochures and other marketing material and provide

input from a medical perspective. Dr. Robinson may give testimony regarding the accuracy and appropriateness of such documents from a medical perspective.

Prior to coming to Ethicon, Dr. Robinson served as a professional education preceptor for Ethicon. In that position, Dr. Robinson trained physicians on pelvic floor surgery using mesh products. Thereafter, in his role as medical affairs director, Dr. Robinson became further involved with Ethicon's professional education program. His responsibilities in that regard involved reviewing professional education material to ensure its accuracy and appropriateness, and to facilitate education. Relying upon this knowledge and experience, Dr. Robinson may provide testimony regarding Ethicon's professional education program, the procedural steps, clinical literature, IFU, complications, success rates, and any other medical portions of the professional education provided for TVT and TVT-O. Dr. Robinson will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships. He may further offer testimony and opinions from the perspective of a professional education trainer prior to coming to Ethicon. Such testimony may specifically include the adequacy of Ethicon's professional education training. Dr. Robinson may also provide testimony on yearly Summits.

In his role as medical affairs director and as a trainer, Dr. Robinson was apprised of the certificates that were provided to professional education trainees, and he will testify that these certificates were simply acknowledgments of attendance and not a certification of the physician's ability to perform the surgery. Dr. Robinson will further opine that it is the surgeon's responsibility to determine whether he or she is capable of performing any surgery, and that credentialing takes place by professional organizations or hospitals, not by manufacturers.

In Dr. Robinson's role as a medical director and as a physician, he is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. Robinson may offer testimony and opinions about the design of the TVT devices and how they safely traverse the pelvic floor. Dr. Robinson may also provide testimony why the Prolene Mesh was, correctly, never changed.

Additionally, in both his clinical practice and in his role as medical affairs director, Dr. Robinson assessed the tissue reaction, integration, contraction and compliance of mesh in-vivo, and determined that the benefits of TVT-O outweighed the risks. Dr. Robinson may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolene mesh in the TVT devices integrates well in the body, that contraction rates are not clinically significant and cannot be compared to other more-invasive surgeries, and that TVT-O is appropriately compliant in the body.

Dr. Robinson also assessed complication rates for TVT and TVT-O while in clinical practice and at Ethicon. Dr. Robinson will also testify, based upon his clinical practice and review of the adverse event reports and literature, as to the rate of occurrence of adverse events, and why he believes that serious complication rates are uncommon.

In Dr. Robinson's benefit/risk analysis for TVT-O, he assessed that laser cut and mechanical-cut mesh were both appropriate. He further determined and may opine that the laser cut mesh did not cause a clinically significant impact on patients and that any particle loss associated with mechanical cut mesh likewise had no clinical effect on patients. Dr. Robinson may also testify regarding any other documents for which he provided medical support or input.

THIS, the 21st day of March, 2014.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION MDL NO. 2327

Tonya Edwards and Gary Edwards,
Plaintiffs,

v. Case No. 2:12-cv-09972

Ethicon, Inc. et al., Defendants

DEFENDANTS' NON-RETAINED EXPERT DISCLOSURES

Defendants Ethicon, Inc. and Johnson & Johnson, pursuant to Pretrial Order #73 and F.R.C.P. 26(a)(2)(c), provide the following written disclosures for Dr. Piet Hinoul, Dr. Axel Arnaud, and Dr. David Robinson.[1]

Dr. Piet Hinoul

Dr. Piet Hinoul will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a urogynecologist and Ethicon Medical Director, his clinical experience, review of literature, and the deposition testimony he has given in this litigation. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705.

Dr. Hinoul is a trained urogynecologist who has implanted hundreds of TVT devices, has performed hundreds of stress urinary incontinence (SUI) procedures, and has provided training and been involved with the training on the TVT products. While a clinician, Dr. Hinoul's

[1] A separate disclosure will be served concerning the testimony of Dr. Thomas Barbolt.

clinical practice included the repair of incontinence and pelvic floor repairs for women. He has served as an investigator and author on several studies and publications involving mid-urethral slings. In 2008, Dr. Hinoul joined Ethicon as the medical affairs director, with responsibilities for pelvic floor repair and incontinence repair products. His duties as medical director included making benefit/risk analyses of devices, drafting clinical evaluation reports, assessing clinical literature, speaking at panel meetings, reviewing adverse events, new product development, corresponding with physicians regarding the use of incontinence and pelvic floor products and providing medical input on the Instructions for Use (IFU), patient brochures, marketing professional education and design verification materials, and other Ethicon documents needing medical affairs' input.

Dr. Hinoul was trained on incontinence repairs including the TVT devices, and the associated risks. In addition to this training, Dr. Hinoul has performed hundreds of SUI repairs, including the TVT devices, has kept apprised of the literature on TVT and other SUI repairs, and has reviewed adverse event reports for these and other procedures. As a result, Dr. Hinoul knows the appropriate indications, procedural steps, warnings and adverse events that would be associated with the TVT devices, and he is expected to testify that the TVT-O IFU is appropriate.

As a practicing urogynecologist and as medical affairs director for Ethicon, Dr. Hinoul has personally determined that the benefits of TVT-O far outweigh the risks. In reaching this determination, he relied upon his clinical experience, training, education, cadaver labs, his review of the applicable literature and the documents that led to the launch of TVT and TVT-O. In his role as medical affairs director, Dr. Hinoul has prepared clinical expert reports on the TVT devices including the TVT-O and has provided medical advice on the benefit/risk assessment of

TVT-O. Dr. Hinoul agrees with the current literature and published professional organization position statements that TVT and TVT-O along with other mid-urethral slings are the standard of care, gold standard and treatment of choice for the surgical treatment of SUI in women, and they have been so for many years.

Dr. Hinoul is expected to provide testimony as to Ethicon's basis for manufacturing and selling TVT and TVT-O. More specifically, incontinence is a prevalent condition that can severely affect a woman's quality of life. Ethicon desired to provide a product that would help women. The surgical procedures available to treat SUI before the TVT devices were developed (Burch colposuspension, fascial slings, Marshall-Marchetti-Kranz, colporrhaphy and other procedures) were associated with increased morbidity, longer recovery times, lower success rates and lack of long-term durability. Dr. Hinoul may also provide testimony regarding other SUI procedures and why the TVT devices are an important and appropriate treatment option compared to those other procedures. In working with Dr. Ulmsten, Ethicon wanted to provide a device that would change the way incontinence was treated, and to present women with a minimally invasive, safe, effective, and durable repair.

Dr. Hinoul will provide the history of the development of the TVT and TVT-O. Dr. Hinoul will testify that Dr. Ulmsten assessed several different meshes to determine which was the most appropriate for SUI repair, and he concluded that it was the Prolene mesh. Using an integral theory, applying the Prolene mesh tension-free in the mid-urethra, with a retropubic approach, Dr. Ulmsten developed the TVT. The Prolene mesh had been used in the human body since 1974, and in sutures since 1969, for cardiovascular repair and many other surgical procedures. The mesh had been used safely in the body for decades, and Dr. Ulmsten demonstrated its success in supporting the mid-urethra. Dr. Ulmsten performed several clinical

trials in which TVT was shown to be safe and effective. In 1997, Ethicon sold TVT in Europe. Then in 1998, with the support of over two years of data, several clinical studies and demonstrated success in Europe, Ethicon began to sell TVT in the United States. Ethicon entered into agreements with Dr. Ulmsten's company, Medscand, to sell the TVT. Dr. Hinoul will testify that these agreements did not alter the factual data presented in the 1998 multi-center study. He will also testify that the universe of data available today further confirms the outcomes of Ulmsten's early studies. By the early 2000s, there was 5-year data and numerous published articles identifying TVT as the "gold standard" for surgical SUI repair, and TVT remains the "gold standard" today.

Dr. Hinoul may also testify that, in 2001, a transobturator approach to treat SUI was developed and sold by American Medical Systems. This approach provided physicians the option of a mid-urethral sling with a transobturator "outside in" approach. Dr. DeLeval subsequently began using the Prolene Mesh for a transobturator sling with an inside out approach. Ethicon working with Dr. DeLeval developed the TVT-Obturator (TVT-O) which was cleared by the FDA and sold in January 2004. Dr. Hinoul will opine that mid-urethral slings with either a retropubic or obturator pass, which include TVT and TVT-O, are the standard of care for SUI repair. He will further opine that TVT and TVT-O provide physicians with two safe and effective approaches to correct SUI, and both remain on the market today.

Dr. Hinoul will testify that there many long term studies on the TVT and TVT-O, which include over 100 RCTs on TVT, 60 RCTs on TVT-O, over 1000 studies on the TVT devices and over 2000 on mid-urethral slings. TVT is the most studied device for the surgical treatment of SUI, with the longest period of supporting clinical data. The major professional societies for the treatment of SUI (American Urological Association, American Urogynecologic Society,

International Urogynecology Association, International Incontinence Society, National Institute of Health and Care Excellence, the British Association of Urological Surgeons, SUF, and other professional organizations) uniformly hold that mid-urethral slings are the treatment of choice, standard of care or gold standard for SUI. The studies have further shown that TVT and TVT-O have an overall positive effect on sexual function, in some cases relieve urge incontinence, is effective in obese patients, provide significant improvement in quality of life, are safe and effective, and can be – and have been – used across the world with great results.

Dr. Hinoul came to Ethicon shortly before publication of the 2008 Public Health Notice and he spoke at the September 2011 FDA ADCOM hearings following publication of the 2011 Public Health Notice. He will provide testimony regarding Ethicon's responses to such Public Health Notices, and he is expected to opine that FDA limited the warnings such that they do not include mid-urethral slings. Further, that the FDA came out with a position statement in 2013 that the multi-incisional slings (including TVT and TVT-O) are safe, effective and have low erosion rates.

In Dr. Hinoul's position as medical affairs director for Ethicon, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Hinoul will testify that physicians must use their training, experience and education when reading an IFU and when implanting TVT-O or any other device. Dr. Hinoul will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the TVT-O IFU was appropriately written as to the sections for: indications, procedural steps, warnings, adverse reactions, contraindications and actions. More specifically, the IFU properly indicates TVT-O to correct urethral hypermobility and intrinsic sphincter deficiency leading to SUI. There are numerous

studies supporting the use of TVT and TVT-O for the repair of both mechanisms of SUI. Dr. Hinoul will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons who are trained to treat SUI and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Hinoul will provide testimony regarding the procedural steps for TVT-O and the reasons why the procedural steps were provided as they were. He will also provide testimony as to how Ethicon instructed physicians to place and adjust the TVT mesh, and to ensure the mesh is placed tension-free under the urethra.

Dr. Hinoul will provide testimony regarding the adequacy of the contraindication, warnings, the adverse reactions, and actions sections. He will specifically provide testimony as to why specific warnings and adverse reactions were or were not provided. Further, Dr. Hinoul will testify that the IFU is intended to identify the specific adverse reactions that may occur from the TVT-O device, and he will opine that the TVT-O IFU did so. Dr. Hinoul will further testify that chronic pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs.

In Dr. Hinoul's position as medical affairs director he is sometimes called upon to participate in the copy-review of patient brochures and other marketing material and provide input from a medical perspective. Dr. Hinoul may give testimony regarding the accuracy and appropriateness of such documents from a medical perspective.

Prior to coming to Ethicon, Dr. Hinoul served as a professional education preceptor for Ethicon. In that position, Dr. Hinoul trained physicians on pelvic floor surgery using mesh products. Thereafter, in his role as medical affairs director, Dr. Hinoul became further involved

with Ethicon's professional education program. His responsibilities in that regard involved reviewing professional education material to ensure its accuracy and appropriateness, and to facilitate education. Relying upon this knowledge and experience, Dr. Hinoul may provide testimony regarding Ethicon's professional education program, the procedural steps, clinical literature, IFU, complications, success rates, and any other medical portions of the professional education provided for TVT and TVT-O. Dr. Hinoul will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships. He may further offer testimony and opinions from the perspective of a professional education trainer prior to coming to Ethicon. Such testimony may specifically include the adequacy of Ethicon's professional education training. Dr. Hinoul may also provide testimony on yearly Summits.

In his role as medical affairs director, Dr. Hinoul was apprised of the certificates that were provided to professional education trainees, and he will testify that these certificates were simply acknowledgments of attendance and not a certification of the physician's ability to perform the surgery. Dr. Hinoul will further opine that it is the surgeon's responsibility to determine whether he or she is capable of performing any surgery, and that credentialing takes place by professional organizations or hospitals, not by manufacturers.

In Dr. Hinoul's role as a medical director and as a physician, he is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. Hinoul may offer testimony and opinions about the design of the TVT devices and how they safely traverse the pelvic floor. Dr. Hinoul was also involved in the continued studies of the mesh that was used in TVT and TVT-O, as well as other potential new meshes for SUI. Dr. Hinoul, on behalf of Ethicon, assessed lighter weight meshes for TVT and

TVT-O including but not limited to TVT-O PA and Scion, and determined that they were inferior in the support they provided, their placeability, and their configuration once implanted. Dr. Hinoul will further testify on behalf of Ethicon's medical affairs as to why Ethicon continued to use the Prolene mesh in the TVT devices instead of adopting a different mesh. Dr. Hinoul has continued to review the literature on other procedures and devices including laparoscopic burch and fascial slings, and has concluded that TVT-O and other mid-urethral slings remain the treatment of choice.

Dr. Hinoul may provide testimony with regard to the pore size and weight of the Prolene mesh, including the other material characteristics of other meshes on the market to be able to show that Ethicon still has one of the largest pore meshes on the market, and that the weight and strength of the Prolene Mesh is necessary to properly support the urethra to prevent incontinence.

Additionally, in both his clinical practice and in his role as medical affairs director, Dr. Hinoul assessed the tissue reaction, integration, contraction and compliance of mesh in-vivo, and determined that the benefits of TVT and TVT-O outweighed the risks. Dr. Hinoul may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolene mesh in TVT and TVT-O integrates well in the body, that contraction rates are not clinically significant and cannot be compared to other more-invasive surgeries, and that TVT is appropriately compliant in the body.

Dr. Hinoul also assessed complication rates for the TVT devices while in clinical practice and at Ethicon. Dr. Hinoul may therefore testify about the adverse reactions that are associated with the TVT and TVT-O and other surgical procedures to show why Ethicon continues to believe that the benefits of TVT-O outweigh the risks. Dr. Hinoul will also testify, based upon

his clinical practice and review of the adverse event reports and literature, as to the rate of occurrence of adverse events, and why he believes that serious complication rates are uncommon. More specifically, Dr. Hinoul will opine that both the applicable literature and his experience in practice support an overall 1-2% exposure rate for TVT. He will further testify that, of the 1-2%, some exposures can be treated conservatively or with no treatment at all, while other patients may need to have a small portion of the mesh excised. Dr. Hinoul will testify that it is extremely rare that the whole of the mesh must be taken out. Groin pain with the TVT-O and other obturator slings is usually transient, and persistent groin pain is a low risk that is warned of. Dr. Hinoul will testify bladder perforations are largely avoided with the TVT-O. Dr. Hinoul will provide testimony regarding all potential complications along with the success and safety data on the TVT and TVT-O.

In Dr. Hinoul's benefit/risk analysis for TVT and TVT-O, he assessed that laser cut and mechanical-cut mesh were both appropriate, and there is not clinical evidence that either product is safer than the other. He further determined and may opine that the laser cut mesh did not cause a clinically significant impact on patients and that any particle loss associated with mechanical cut mesh likewise had no clinical effect on patients. Dr. Hinoul will further testify that degradation, if it exists, is not clinically significant and there are not studies to show degradation, even if it were to exist causes any harm to patients. It is this Prolene mesh that has been used in hernia meshes for decades safely.

Dr. Hinoul may also testify, from a design perspective, to any design documents for TVT and TVT-O, or any other topic on which he has been identified as a corporate witness on behalf of Ethicon.

Dr. Axel Arnaud

Dr. Axel Arnaud will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a general surgeon and as European Ethicon Medical Director, his clinical experience, his review of literature, and the deposition testimony he has given in this litigation. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705. In addition, any portion of Dr. Arnaud's deposition testimony concerning these matters or the matters identified below may be designated by Ethicon for use at trial, and such deposition testimony may likewise involve or require scientific, technical or specialized knowledge falling within the scope of F.R.E. 702, 703, or 705.

Dr. Axel Arnaud obtained his medical degree in 1978, and completed his residency in surgery for general and digestive surgery in 1984 at the University of Merseille. Dr. Arnaud was an assistant professor of anatomy from 1979-1981 and an assistant professor of general and digestive surgery from 1984-1988. Dr. Arnaud was a practicing surgeon in France until he joined Ethicon in 1992. Dr. Arnaud held the positions of Director of Research and Development until 1999, Scientific Director for Ethicon Europe until 2001, Scientific Director for Gynecare Europe until 2008, Medical Affairs Director for Ethicon EMEA until 2013, and he is currently the Medical Affairs Group Director for Global Surgery EMEA.

As a practicing clinician, Dr. Arnaud was responsible for making benefit/risk analyses regarding medical devices. His duties as a European medical director for Ethicon further included making benefit/risk analyses of devices including TVT and TVT-O, assessing clinical literature, speaking at panel meetings, and providing medical input on the Instructions for Use (IFU) and other Ethicon documents needing medical affairs' input.

Dr. Arnaud's surgical experience, review of medical literature, experience with cadaver labs, review of SUI procedures, and consultations with other experts in SUI repair has given him the expertise to identify the appropriate indications, procedural steps, warnings and adverse events that would be associated with the TVT devices, and he is expected to testify that the TVT-O IFU is appropriate.

As a surgeon and as the European medical affairs director for Ethicon, Dr. Arnaud determined that the benefits of TVT and TVT-O far outweigh the risks. Dr. Arnaud further agrees with the current literature and published professional organization statements that TVT and other mid-urethral slings including TVT-O are the standard of care for the surgical treatment of SUI in women, and they have been so for many years.

Dr. Arnaud is expected to provide testimony as to Ethicon's basis for manufacturing and selling TVT and TVT-O. More specifically, he will testify that incontinence is a prevalent condition that can severely affect a woman's quality of life. Ethicon desired to provide a product that would help women. The surgical procedures available to treat SUI before the TVT devices were developed were associated with increased morbidity, longer recovery times, lower success rates and a lack of long-term durability. Dr. Arnaud may also provide testimony as to why the TVT devices are an important and appropriate treatment option for women with SUI.

Dr. Arnauld will testify concerning the history and development of TVT and TVT-O. Dr. Arnaud will testify regarding his meetings with Dr. Ulmsten, his opinions of TVT when it was demonstrated for him, and the reasons why he encouraged Ethicon to support Dr. Ulmsten in marketing TVT globally. Dr. Ulmsten and Ethicon wanted to provide a device that would change the way incontinence was treated, and to present women with a minimally invasive, safe,

effective, and durable repair. Dr. Ulmsten assessed several different meshes to determine which was the most appropriate for SUI repair, and he concluded that it was the Prolene mesh. Using an integral theory, applying the Prolene mesh tension-free in the mid-urethra, with a retropubic approach, Dr. Ulmsten developed the TVT. The Prolene mesh had been used in the human body since 1974, and in sutures since 1969, for cardiovascular repair and many other surgical procedures. The mesh had been used safely in the body for decades, and Dr. Ulmsten further demonstrated its success in supporting the mid-urethra. Dr. Arnaud visited with Dr. Ulmsten, watched the procedures, spoke with patients, communicated with outside consultants, and determined that the TVT procedure was safe, effective and would revolutionize the way in which SUI repairs were performed.

Dr. Ulmsten performed several clinical trials in which TVT was shown to be safe and effective. In 1997, Ethicon sold TVT in Europe. The feedback regarding the safety and effectiveness was outstanding. Then in 1998, with the support of over two years of data, several clinical studies and demonstrated success in Europe, Ethicon began to sell TVT in the United States. Ethicon entered into agreements with Dr. Ulmsten's company, Medscand, to sell the TVT. Dr. Arnaud will testify that these agreements did not alter the factual data presented in the 1998 multi-center study. He will also testify that the universe of data available today further confirms the outcomes of Ulmsten's early studies. By the early 2000s, there was 5-year data and numerous published articles identifying TVT as the "gold standard" for surgical SUI repair. Dr. Arnaud will testify that TVT remains the worldwide "gold standard" today.

Dr. Arnaud may also testify that, in 2001, a transobturator approach to treat SUI was developed and sold by American Medical Systems. This approach provided physicians the option of a transobturator pass to place a mesh sling below the mid-urethra. In 2002, Dr. Arnaud

met with Dr. DeLeval about an inside-out transobturator approach. Dr. Arnaud reviewed the procedure, brought in experts, reviewed literature and data, and determined it was a safe and effective procedure. In 2003, Ethicon began to sell the TVT-Obturator (TVT-O), which was an inside-out transobturator approach. Dr. Arnaud will opine that mid-urethral slings with either a retropubic or transobturator pass, including TVT and TVT-O, are the standard of care for SUI repair. He will further opine that TVT and TVT-O provide physicians with two safe and effective approaches to correct SUI. Both remain on the market today.

Dr. Hinoul will testify that there many long term studies on the TVT and TVT-O, which include over 100 RCTs on TVT, 60 RCTs on TVT-O, over 1000 studies on the TVT devices and over 2000 on mid-urethral slings. TVT is the most studied device for the surgical treatment of SUI, with the longest period of follow-up data. The major professional societies for the treatment of SUI (American Urological Association, American Urogynecologic Society, National Institute of Health and Care Excellence, International Continence Society, International Urogynecology Association, British Association of Urological Surgeons, SUFU and others) uniformly hold that mid-urethral slings are the treatment of choice, standard of care and gold standard for SUI. The studies have further shown that TVT and TVT-O have an overall positive effect on sexual function, in some cases relieve urge incontinence, are appropriate in obese women, are safe and effective, and can be – and have been – used across the world with great results.

In Dr. Arnaud's position as European medical affairs director, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Arnaud will testify that physicians must use their training, experience and education when reading an IFU and when implanting TVT-O or any

other device. Dr. Arnaud will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the TVT-O IFU was appropriately written. Dr. Arnaud will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons who are trained to treat SUI and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Arnaud will provide testimony regarding the adequacy of the warnings and adverse reactions in the IFU. Further, Dr. Arnaud will testify that the IFU is intended to identify the specific adverse reactions that may occur from the TVT-O device, and he will opine that the TVT-O IFU did so. Dr. Arnaud will further testify that pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs.

Dr. Arnaud may provide testimony regarding Ethicon's decision to make laser cut mesh an option, and he will opine that laser cut and mechanical cut mesh did not lead to clinically significant differences, and that the mechanical cut mesh was appropriate for use in the body, as the long term data provides.

Dr. David Robinson

Dr. David Robinson may provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a pelvic floor surgeon and Ethicon Medical Director, his clinical experience, review of literature, and the deposition testimony he has given in this litigation. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705. In addition, any portion of Dr. Robinson's deposition testimony concerning these matters or the matters identified below may be designated by Ethicon for use at trial, and such deposition testimony may likewise involve or require scientific, technical or specialized knowledge falling within the scope of F.R.E. 702, 703, or 705.

Dr. Robinson performed a residency in obstetrics and gynecology and completed additional training for pelvic floor surgery. He has implanted hundreds of TVT devices, has performed hundreds of stress urinary incontinence (SUI) procedures, and has trained physicians to use the TVT products. Dr. Robinson's clinical practice included the repair of incontinence for women. He has also served as an investigator for pelvic mesh repair studies. In 2005, Dr. Robinson joined Ethicon as the medical affairs director, with responsibilities for pelvic floor repair and incontinence repair products. His duties as medical director included making benefit risk analyses of devices, drafting clinical evaluation reports, assessing clinical literature, speaking at panel meetings, reviewing adverse events, and providing medical input on the Instructions for Use (IFU), patient brochures, marketing professional education and design verification materials, and other Ethicon documents needing medical affairs' input.

Dr. Robinson was trained on incontinence repairs including TVT and TVT-O, and the associated risks. In addition to this training, Dr. Robinson performed hundreds of SUI repairs, including TVT, kept apprised of the literature on TVT and other SUI repairs while an active

surgeon and in the role of medical affairs director overseeing pelvic floor products, and has reviewed adverse event reports for TVT and other pelvic devices during his time as medical director overseeing pelvic floor products. As a result, Dr. Robinson knows the appropriate indications, procedural steps, warnings and adverse events that would be associated with the TVT devices, and he is expected to testify that the TVT-O IFU is appropriate.

As a practicing surgeon for pelvic floor defects including urinary incontinence and as medical affairs director for Ethicon, Dr. Robinson personally determined that the benefits of TVT-O far outweigh the risks. In reaching this determination, he relied upon his clinical experience, training, education, experience with cadaver labs, and his review of the applicable literature and the documents that led to the launch of TVT and TVT-O. In his role as medical affairs director, Dr. Robinson has prepared clinical expert reports on TVT and TVT-O and has provided medical advice on the benefit risk assessment of TVT. Dr. Robinson agrees with the current literature and published professional organization statements that TVT and other mid-urethral slings including TVT-O are the standard of care for the surgical treatment of SUI in women, and they have been so since the early 2000s.

Dr. Robinson may provide testimony as to Ethicon continuing to manufacture and sell TVT and TVT-O, and why Dr. Robinson provided TVT and TVT-O to his patients. More specifically, he will testify that incontinence is a prevalent condition that can severely affect a woman's quality of life. Ethicon desired to continue to provide a product that would help women. The other surgical procedures available to treat SUI (Burch colposuspension, fascial slings, Marshall-Marchetti-Kranz, colporrhaphy and other procedures) were associated with increased morbidity, longer recovery times, lower success rates and lack of long-term durability. Dr. Robinson may also provide testimony regarding those other SUI procedures and why the

medical affairs department believed the TVT devices were an important and appropriate treatment option compared to them. Dr. Robinson is further expected to opine that non-surgical options for more severe SUI do not provide long-lasting success.

Dr. Robinson will testify that by the early 2000s, there was 5-year data and numerous published articles identifying TVT as the "gold standard" for surgical SUI repair, and he will opine that TVT continued to be the gold standard while he was in his role as medical affairs director.

Dr. Robinson will testify that there was, numerous RCTs and multiple other studies that supported Ethicon's continued sale of TVT and TVT-O while Dr. Robison was medical director. Further, Dr. Robinson will testify that TVT and TVT-O were and still are the most studied devices for the surgical treatment of SUI, with the longest period of supporting clinical data. The major professional societies for the treatment of SUI (American Urological Association, American Urogynecologic Society, National Institute of Health and Care Excellence, International Urogynecological Association, International Continence Society, SUFU and others) uniformly hold that mid-urethral slings are the repair of choice for SUI. The studies have further shown that TVT and TVT-O do not have an overall negative effect on sexual function, in some cases relieve urge incontinence, and can be – and have been – used across the world with great results.

In Dr. Robinson's position as medical affairs director for Ethicon, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Robinson will testify that physicians must use their training, experience and education when reading an IFU and when implanting TVT-O or any

other device. Dr. Robinson will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the TVT-O IFU was appropriately written as to the sections for: indications, procedural steps, warnings, adverse reactions, contraindications and actions. More specifically, the IFU properly indicates TVT to correct urethral hypermobility and intrinsic sphincter deficiency leading to SUI. There are numerous studies supporting the use of TVT and TVT-O to repair both mechanisms of SUI. Dr. Robinson will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons, who are trained to treat SUI, and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Robinson will provide testimony regarding the procedural steps for TVT-O and the reasons why the procedural steps were provided as they were. He will also provide testimony as to how Ethicon instructed physicians to place and adjust the TVT mesh, and to ensure the mesh is placed tension-free under the urethra.

Dr. Robinson will provide testimony regarding the adequacy of the warnings, the adverse reactions, and actions sections in the TVT-O IFU. He will also testify as to why specific warnings and adverse reactions were or were not provided. Further, Dr. Robinson will testify that the IFU is intended to identify the specific adverse reactions that may occur from the TVT-O device, and he will opine that the TVT-O IFU did so. Dr. Robinson will further testify that pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs.

In Dr. Robinson's position as medical affairs director he was sometimes called upon to participate in the copy-review of patient brochures and other marketing material and provide

input from a medical perspective. Dr. Robinson may give testimony regarding the accuracy and appropriateness of such documents from a medical perspective.

Prior to coming to Ethicon, Dr. Robinson served as a professional education preceptor for Ethicon. In that position, Dr. Robinson trained physicians on pelvic floor surgery using mesh products. Thereafter, in his role as medical affairs director, Dr. Robinson became further involved with Ethicon's professional education program. His responsibilities in that regard involved reviewing professional education material to ensure its accuracy and appropriateness, and to facilitate education. Relying upon this knowledge and experience, Dr. Robinson may provide testimony regarding Ethicon's professional education program, the procedural steps, clinical literature, IFU, complications, success rates, and any other medical portions of the professional education provided for TVT and TVT-O. Dr. Robinson will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships. He may further offer testimony and opinions from the perspective of a professional education trainer prior to coming to Ethicon. Such testimony may specifically include the adequacy of Ethicon's professional education training. Dr. Robinson may also provide testimony on yearly Summits.

In his role as medical affairs director and as a trainer, Dr. Robinson was apprised of the certificates that were provided to professional education trainees, and he will testify that these certificates were simply acknowledgments of attendance and not a certification of the physician's ability to perform the surgery. Dr. Robinson will further opine that it is the surgeon's responsibility to determine whether he or she is capable of performing any surgery, and that credentialing takes place by professional organizations or hospitals, not by manufacturers.

In Dr. Robinson's role as a medical director and as a physician, he is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. Robinson may offer testimony and opinions about the design of the TVT devices and how they safely traverse the pelvic floor. Dr. Robinson may also provide testimony why the Prolene Mesh was, correctly, never changed.

Additionally, in both his clinical practice and in his role as medical affairs director, Dr. Robinson assessed the tissue reaction, integration, contraction and compliance of mesh in-vivo, and determined that the benefits of TVT-O outweighed the risks. Dr. Robinson may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolene mesh in the TVT devices integrates well in the body, that contraction rates are not clinically significant and cannot be compared to other more-invasive surgeries, and that TVT-O is appropriately compliant in the body.

Dr. Robinson also assessed complication rates for TVT and TVT-O while in clinical practice and at Ethicon. Dr. Robinson will also testify, based upon his clinical practice and review of the adverse event reports and literature, as to the rate of occurrence of adverse events, and why he believes that serious complication rates are uncommon.

In Dr. Robinson's benefit/risk analysis for TVT-O, he assessed that laser cut and mechanical-cut mesh were both appropriate. He further determined and may opine that the laser cut mesh did not cause a clinically significant impact on patients and that any particle loss associated with mechanical cut mesh likewise had no clinical effect on patients. Dr. Robinson may also testify regarding any other documents for which he provided medical support or input.

THIS, the 21st day of March, 2014.

Respectfully submitted,

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